EXTRA PAIN RELIEF- acetaminophen, aspirin and caffeine tablet, film coated TIME CAP LABS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

370R Timely 49483 370 Acetaminophen 250 mg, Aspirin 250 mg (NSAID), and Caffeine 65 mg

DRUG FACTS

Active ingredient (in each caplet)

Acetaminophen 250 mg Aspirin 250 mg (NSAID)* Caffeine 65 mg *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever Pain reliever aid

Uses

temporarily relieves minor aches and pains due to:

headache a cold arthritis muscular aches toothache premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

Stop using and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- you experience any of the following signs of stomach bleeding:

feel faint

have bloody or black stools

vomit blood

have stomach pain that does not get better

ringing in the ears or loss of hearing occurs, consult a doctor before taking any more of this product.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DIRECTIOINS

Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

OTHER INFORMATION

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, pregelatinized starch, povidone, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? call 1-877-290-4008



TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)

Purpose Pain reliever aid

Uses
■ temporarily relieves minor aches and pains due to:
■ headache
■ a cold ■ arthritis ■ muscular aches
■ toothache ■ premenstrual and menstrual cramps

Warnings

Warnings
Rey's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and wonting occur, consult a doctor because these symptoms could be an early sign of Rey's syndrome, a rate but serious liness.

Allerny alert. Aspirin may cause a severa allergic reaction, which may include: ■ hims ■ flacial swelling ■ shock ■ asthma (wheezing)

Allerny alert. Acataminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ loisters ■ rash. If a skin reaction occurs, stop use and seek medical half pinght away. and seek medical help right away. Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 8 caplets in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this recedited.

Drug Facts (continued)

Drug Facts (continued)
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

**Bare age 80 or older have labeleding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription (Saplira, Buyorden, naproxen, or others)

**Bare 30 more actionable drugs developed the seven day while using this product taleate more of or a longer time than directed

Catfeine warning: The recommended dose of this product contains about as much catfeine as a up of coffee. Limit the use of catfeine-containing medications, toods, or beverages while taking this product because to much catfeine may cause errovsuress, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use ■ with any other drug containing use mu use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacst. we for more than 10 days for pain unless directed by a doctor we for more than 3 days for fever unless directed by a doctor.

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Ask a doctor before use if " = stomach bleeding warning applies to you " you have a history of stomach problems, such as heartburn " you have high blood pressure, heart disease, liver cirrhosis or kidney disease " you are taking a diuretic

Ask a doctor or pharmacist before use if you are
taking a prescription drug for diabetes, gout, or
arthritis taking any other drug or are under a
doctor's care for any serious condition

Drug Facts (continued)

Drug Facts (continued)
Stop using and ask a doctor if w symptoms do not improve w new symptoms occur pain or lever persists or gets worse you experience any of the following signs of stomach belong; eller faint have bloody or black stools vomit blood have stomach pain that does not get better in ringing in the sare or loss of heraing occurs, consult a doctor before taking any more of this product.

occir peter taxing any more or this product.

If pregnant or breast-leading, ask a health professional
before use. It is especially important not to use aspirin
during the last 3 months of pregnancy unless definitely
directed to do so by a doctor because it may cause
problems in the unborn child or complications during
delivery.

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Keep out of reach of children. In case of accidental overtose, get medical help or contact a Poison Control Center (1-800-22-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ■ do not use more than directed
■ drink a full glass of water with each dose
■ adults and children 12 years and over: take 2 caplets
every 6 hours; not more than 8 caplets in 24 hours
■ children under 12 years; ask a doctor

Other information store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) use by expiration date on package

Inactive ingredients carnauba wax, colloidal silicon

NDC 49483-370-42 Compare to the active ingredients in Excedrin® Extra Strength†

PAIN RELIEVER

Acetaminophen 250 mg, Aspirin 250 mg (NSAID) and Caffeine 65 mg Pain Reliever / Pain Reliever Aid

24. CAPLETS (Capsule-Shaped Tablet)

4 314

This product is not manufactured or distributed by GlaxoSmithKline pic, owner of the registered trademark Exceptine Extra Strength. 370R 1220 Distributed by Time-Cap Lats, Inc. 7 Michael Avenue, Farmingdale, WY 11735

Drug Facts (continued)
mineral oil, pregelatinized star
starch glycolate, stearic acid, Questions or comments? call 1-877-290-4008 l oil, pregelatinized starch, povidone, sodium glycolate, stearic acid, titanium dioxide



HETAIN CARTON FOR COMPLETE PRODUCT INFORMATION
Uses a temporarily relieves minor aches and pains due to headache, a cold, arthritis, muscular aches, toothache a premenstrual and menstrual cramps.

Wannings See earlon for complete warnings
Reys syndrome: Ohlden and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, it changes in leadardow with nates and vomining occur, consult a doctor because these symptoms could be an early sign of Reys's syndrome, a rate but sertious illness. Allergy alert, Aspaining occur, consult a doctor because these symptoms could be an early sign of Reys's syndrome, a rate but sertious illness. Allergy alert, Aspaining occur, consult a control reaction. Symptoms may include: a live's a facial svelling

a shock a stiffind wither any include: a live's a facial svelling

a shock a stiffind wither any product and live's acts as severe skin reaction occurs, stop uses and seak medical help right away.

Liver warning: This product contains acetaminophen assert liver damage may occur if you take: a more than the adequate and the adequate any could any manual. This product contains a nSAID, which may cause severe stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or otiler all any containing prescription NSAIDs (aspirin, ibuprofen, naproxen, or others) a have be attendable of the chance is higher if you: are age 60 or otiler or or a donger time than directed if pregnant or breast-leeding, ask and or or nomprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) a have be attended and include any spins or symptoms.

An oncomplication or surging to expranging this product a product during elleving and directed to do so by a doctor because if may cause problems in the unborn child or or ordinate a Poison Control Center (1-800-222-1222) right away. Pronth medical arterior is critical to a during a nor or similar directed or a docto

Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735 370R 1120 Lot No.:

Exp. Date:

Facts (continued)

cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems

■ take à blood thinning (anticoagulant) or steroid drug

take other drugs containing prescription or nonprescription NSAIDs

(aspirin, buporden, approxen, or officers)

have 3 or more alcoholic drinks every day while using this product

■ take more or for a longer time than directed. Catheire warming: The recommended dose of this product contains because a much cafeline as a cup of coffee. Limit the use of caffeire-containing medications; toods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, eplessness, and, occasionally, rapid heartbeat

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Tor more than 10 days for pain unless directed by a doctor for more than 3 days for faver unless directed by a doctor

Ask a doctor or pharmacist before use if you are
■ taking a prescription drug for diabetes, gout, or arthritis ■ taking any other drug or are under a doctor's care for any serious condition Ask a doctor before use if stomach bleeding warning applies to
you sub ware a history of stomach problems, such as hearthurn
you have high blood pressure, heard disease, liver cirmosis or kidney
disease you are taking a diuretic

Stop using and ask a doctor it symptoms do not improve a new symptoms occur. So and there possists or gats worse. You experience any of the following signs of stomach bedding feel faint. In have bloody or black stocks. Indiging in the ears or loss of haring occurs, consult a doctor before taking any more of this product. If preparant or breast-feeding, ask a health professional before use, it is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any

children under 12 years: ask a doctor

Other information
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package

NDC 49483-370-20

Compare to the active

ingredients in Excedrin® Extra Strength†

Actual Size

Directions ■ do not use more than directed
■ drink a full glass of water with each dose
■ adults and children 17 years and over: take 2 caplets every 6 hours;
not more than 8 caplets in 24 hours

Inactive ingredients camauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, pregelatinized starch, povidone, sodium starch glycolate, stearic acid, titanium dioxidi.

Questions or comments? call 1-877-290-4008

=tim**ė**ly

Extra Strength

and Caffeine 65 mg

200 CAPLETS**
(**Capsule-Shaped Tablet)

PAIN RELIEVER

Pain Reliever / Fever Reducer

Acetaminophen 250 mg, Aspirin 250 mg (**NSAID**),



Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735

Exp. Date: Lot No.:

Drug Facts (continued under label)

■ more than 8 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

Repris syndrome: Children and beeragers who have or are recovering from chicken door of full-like syndroms should not seek his product. When using this product, it changes in behavior with natissa and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, at are but sentious liness.

Aleryy alert. Aspin may cause a severe allergic reaction, which may include:

I have a facial swelling should sharing when any cause severe sharing when any or any nicutue: mashin reduction cours, stop use and seek medical help inght away.

I her warming. This product contains accelaminophen, Severe liver damage may occur if you take:

nonsteroidal anti-inflammatory drug Saffeine 65 mg.

.....Pain reliever aid

USBS ■ temporarily relieves minor aches and pains due to:

■headache ■ a cold ■ arthritis ■ muscular aches ■ toothache

■premenstrual and menstrual cramps

Active ingredient (in each caplet)

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE CUT, TORN, BROKEN OR MISSING



RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet)

Uses
■ temporarily relieves minor aches and pains due to:

■ toothacke ■ premenstrual and menstrual cramps

Warnings

Warnings

Rey's syndrome: Children and teenagers who have or are recovering from chicken poor of thulke symptoms should not use this product. When using this product, then using this product, then using this product, then using this product, if changes in behavior with nauses and vernifing occur, consult a doctor because these symptoms could be an exity sign of Rey's syndrome, a rare but serious liness.

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Altery alter April more causes as evere eather reactions. Symptoms may include. ■ skin reddening ■ bibsters ■ reach it as kin reaction occurs, stop use and seek medical high right away.

away.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

more than 8 caplets in 24 hours, which is the maximum daily

mourt amount and capiers in 2-rhours, which is use inabilitin daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older

Drug Facts (continued)

Drug Facts (continued)

There had stomant ulcers or bleeding problems

Take a blood thinning (anticoagulant) or steroid drug

Take other drugs containing restriction or nonprescription

NSAIDs (septini, buporden, approxen, or others)

There are no steroid or the steroid or the steroid or the steroid or the steroid or thin severy by while using this product

Take more or for a longer time than directed

Caffeline warning: The recommended dose of this product

Caffeline variation medications, foods or breampts while taking this product because from much daffere may cause

recoverses; ministrying medications, foods or bewanges while taking this product because from much afferie may cause

recoverses; ministrying, seeplessness, and, coussionally, radio

of calleter-containing ineutrations, looks, or leverlages writer lating this product because for much radien any cause nervousiess, irribality, slepitessness, and, occasionally, rapid harribast.

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

In or more than 10 days for pain unless directed by a doctor or for more than 3 days for fever unless directed by a doctor.

Ask a doctor before use if a stomach bedenity warming applies to you a you have history of stomach problems, such as hearthum a you have high bodd pressure, heat disease, liver criminosis or idding disease. Buy our are taking a duretic.

Ask a doctor a pharmacist before use if I you are a taking a prescription drug for diabetes, gout, or arthritis a taking any other drug or are under a doctor's care for any serious condition.

Acetaminophen 250 mg, Aspirin 250 mg (NSAID), and Caffeine 65 mg

100 ("Capsule-Shaped Table Pain Reliever / Pain Reliever Aid

senous condition

Stop using and ask a doctor if

symptoms do not improve

new symptoms occur

pain or fever persists or gets worse

you experience any of the following signs of stomach
bleeding:

new feel faint

have bloody or black stools

womit blood

have stoody or black stools

womit blood

have stoody or black stools

womit blood

have stoody or black stools

Extra Strength PAIN RELIEVER =+imôly

Drug Facts (continued)

ringing in the ears or loss of hearing occurs, consult a doct before taking any more of this product.

before taking any more of this product.

If pregnant to reach-feeting, ask a baship notessional before
use. It is superbally important not to use aspirin during the last 3
months of pregnating valents definitely directed to do so by a
director because it may cause problems in the unborn child or
complications during delivery.

Keep out of reach of children.

The case of accidental overdose, get medical help or contact a
Poison Control Center (1-800-222-1222) right away. Prompt
medical attention is critical for adults well sor children even if
you do not notice any signs or symptoms.

Directions
do not use more than directed
drinks a full glass of water with each dose
adults and children 12 years and over take 2 caplets every 6
hours, not more than 6 caplets in 24 hours
whildren under 12 years: ask a doctor

Other information
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ use by expiration date on package

Inactive ingredients carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, pregelatinized starch, povidone, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? call 1-877-290-4008

This product is not manufactured or distributed by GlaxoSmithKline pic, owner of the registered trader Excedin® Extra Strength. 370 Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735



Acetaminophen 250 mg,Aspirin 250 mg **(NSAID)**), and Caffeine 65 mg Pain Reliever / Pain Reliever Aid

PAIN RELIEVER

Compare to the active ingredients in Excedrin® Extra Strength[†]

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NDC 49483-370-01

CAPLETS**
("Capsule-Shaped Tablet)

NDC 49483-370-01 =timely

Extra Strength PAIN RELIEVER

Acetaminophen 250 mg, Aspirin 250 mg (NSAID), and Caffeine 65 mg

Pain Reliever / Pain Reliever Aid

100 CAPLETS**
(**Capsule-Shaped Tablet)

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

arthritis, muscular aches, totolable = premetstrual and menstrual cramps
Marnings See earton for complete warnings
Reps syndrome. Children and teaches = premetstrual and menstrual cramps
Marnings See earton for complete warnings
Reps syndrome. Children and teaches warnings
Reps syndrome. Children and teaches was who lave or are recovering from children
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Reps syndrome. Children and teachers who lave or are recovering from children
Reps syndrome. Children and teachers who lave or are put serious illness.

Allergy after, Cyptim mis causes abered being reaction, which may include:

* Inches warning: This product contains calcaminophen. Several lengthanage may occur
if you take. ** a tick stack and the state of the standard product or cours, stop uses and seek medical help right away.

It was warning: This product contains acataminophen. Several lengthanage may occur
if you take. ** a more than 8 capites in 24 hours, which is the maximum daily amount
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if you take. ** a more than 8 capites in 24 hours, which is the maximum daily amount
if you take. ** a more activation of day while using this product or manta some activation. ** Short Somethy in the bending problems: ** alke a Nore or for a longer time than directed
day while using this product ** at least product contains and a much cartiene as a upp of coffer. I mit the use of rafferier-containing medications, hoods, or
deverges while taking this product ** at least product because to much cartiene may cause
nevousness, straining the secondard and secondard or complications during delivery.

Keep out or reach of fulliers. I may cause problems in the unborn child or
complications during delivery.

Keep out or reach of fulliers in Lase of accidental overdoses, and cocated in developers. It is especially
important to the so spir in during the last 3 monitors of programs through the cause in or for a longer tim

Directions ■ do not use more than directed
■drink at lul gissor where with each doer take 2 capies every 6 hours; not more than
adults and children 12, years and over take 2 capies every 6 hours; not more than 8 capies in 24 hours. ■ children under 12 years, ask a doctor

SEAL

Other information

Tuber informa

Date:

EXTRA PAIN RELIEF

acetaminophen, aspirin and caffeine tablet, film coated

Product	Inform	ation
Product		ation

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients			
Ingredient Name	Strength		
STEARIC ACID (UNII: 4ELV7Z65AP)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
MINERAL OIL (UNII: T5L8T28FGP)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE ((CAPSULE SHAPED TABLET))	Size	18mm
Flavor		Imprint Code	TCL370
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483- 370-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2021	
2	NDC:49483- 370-20	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2013	
3	NDC:49483- 370-00	20000 in 1 CARTON; Type 0: Not a Combination Product	02/22/2016	
4	NDC:49483- 370-42	1 in 1 CARTON	07/16/2021	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part343	11/01/2013		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Labeler - TIME CAP LABS (037052099)

Registrant - TIME CAP LABS (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABS		037052099	manufacture(49483-370)	

Revised: 7/2021 TIME CAP LABS